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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/345,373	07/01/1999	STEVEN M. RUBEN	1488.036000A	1167

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/04/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/345,373

Applicant(s)
RUBEN et al.

Examiner
Christine Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 8, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 183-200 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 183-200 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 08 August 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/345,373 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

2. Claims 183, 189 and 195 have been amended and claims 43-45, 94-126 and 135-182 have been canceled as requested in the amendment of paper #16, filed 17 July 2002 (entry requested in the CPA). Claims 183-200 are pending in the instant application.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed 17 July 2002 have been fully considered but they are not deemed to be persuasive.

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Information Disclosure Statement

6. The IDS which was filed 25 September 2002 (paper #19) appears to be a duplicate of that which was filed 04 May 2000 (paper #4). It has been placed into the file, but indicated to be a duplicate paper.

Double Patenting

7. Applicant should note that there are several applications and/or patents with which the instant application may have conflicting subject matter. As the instant claims include the functional language of "wherein said polypeptide binds to an antibody that specifically binds a polypeptide consisting of the amino acids Ser (69) - Ser (208) of SEQ ID NO:2", the rejections over the other applications/patents is not applicable. However, this function in conjunction with the percent identity language is considered new matter, and if it is canceled from the claims, the double patenting rejections would be appropriate. These would be considered new grounds of rejection necessitated by Applicant's amendment. The applications/patents at issue are 10/075,446, 6,077,692 and 6,238,888.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 183-200 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claims are directed to polypeptides which have some degree of amino acid sequence identity to a portion of SEQ ID NO:2 and wherein the polypeptides binds an antibody which specifically binds the polypeptide of SEQ ID NO:2. The instant specification fails to contemplate these polypeptides in that the inventive concept of such a polypeptide is not found in the instant specification as originally filed. First, the specification fails to contemplate a polypeptide which has some degree of sequence identity to a polypeptide of Ser (69) - Ser (208) of SEQ ID NO:2. The specification at pages 9-10 only contemplates polypeptides with some degree of sequence identity to (1) the full length protein of SEQ ID NO:2 (or that of the deposit) or (2) the "mature" protein of SEQ ID NO:2 (or that of the deposit), wherein the N-terminus is at approximately amino acid 36. There is no disclosure of percent sequence identity in conjunction with the polypeptide comprising amino acids 69-208 of SEQ ID NO:2. Secondly, there is no disclosure of percent sequence identity in conjunction with a polypeptide that binds an antibody that specifically binds the polypeptide of SEQ ID NO:2. The instant specification contemplates antigenic portions (see pages 32 and 37-41), but not the broader invention of polypeptides which contain mutations and which bind antibodies that specifically bind a polypeptide of SEQ ID NO:2. While percent identity would encompass small truncations and therefore, contiguous portions of

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SEQ ID NO:2, the recitation of percent identity also encompasses point mutations, deletions and insertions, wherein this concept does not find support in the instant specification as filed.

10. Claims 183-200 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims encompass polypeptides having at least 90, 95, or 97% sequence identity to SEQ ID NO:2, wherein the polypeptide binds an antibody which specifically binds a polypeptide of SEQ ID NO:2. The instant specification fails to describe any polypeptides which meet these limitations of the claims. First, the instant specification teaches a single example of a polypeptide (SEQ ID NO:2), and fails to teach any other polypeptides having the recited % identity to SEQ ID NO:2 and the claimed function. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a protein which has the amino acid sequence of SEQ ID NO:2. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed to polypeptide which have

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sequence identity to the disclosed polypeptide of SEQ ID NO:2 and having a specific function of binding an antibody which specifically binds to a polypeptide of SEQ ID NO:2. First, the claims are not limited to any particular polypeptide, in that the claims are directed to variant forms. The specification only describes a single polypeptide and fails to teach or describe any other molecules which meet the structural limitations of the claims. The breadth of the claims is such that the claims encompass polypeptides from other species, related polypeptides and variants which have yet to be described. There is a lack of guidance or teaching regarding structure and function of the polypeptide because there is only a single example of a polypeptide provided in the specification and because there is no guidance found in the prior art for this specific polypeptide.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polypeptide of SEQ ID NO:2. The specification does not provide a complete structure of those molecules which have the recited % sequence identity to SEQ ID NO:2 and retain the required function of the claims. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms

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that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus because the specification teaches a single embodiment. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

11. Claims to an isolated polypeptide comprising an amino acid sequence identical to Ser (69) - Ser (208) of SEQ ID NO:2 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud